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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,503	05/31/2001	Lawrence R. Green	033599-019	2081
21839	7590	06/13/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MOSHER, MARY	
POST OFFICE BOX 1404				
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 06/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/872,503

Applicant(s)

GREEN ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/29/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/31/2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The documents BM, BP, and CF still have not been considered, as no copies were yet available. Applicant's intent to furnish copies is noted.

### ***Claim Rejections - 35 USC § 112***

Claims 31-47 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for augmenting vaccination in a fish using HM897 peptide (Thr-Ala-Glu-Glu-Lys), does not reasonably provide enablement for the full scope of augmenting vaccination in any host using any 2-9 residue peptide comprising Glu-Lys or Gln-Lys. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for reasons of record.

Applicant argues that the specification provides examples with regard to mammals, examples 1-4 report experiments with guinea pigs and examples 7-8 report experiments in mice. However, these mammal experiments dealt with aspects of the immune system other than augmentation of response to a vaccine. Applicant further argues that the immune systems of fish and mammals are in fact very similar. However, the specification provides evidence that the immune systems of fish and mammals differ in how they are affected by HM897, because example 9 shows that HM897 induces a rapid (presumably nonspecific) resistance to bacterial infection in mice, whereas example 10, group V does not shows similar resistance in fish.

In regard to the scope of the peptides use, applicants argue that a variety of peptides are discussed in the specification and can be shown to have immunomodulating activities, pointing to pages 5-7 for structural and functional guidance and preferred substituents. The specification asserts broad immunomodulating effects, and discusses preferred embodiments of peptides, but does not provide any guidance as to how modification of the peptide structure affects augmentation of the response to a vaccine. Therefore, considering the unpredictability of the art, as indicated in the previous office action, it is maintained that undue experimentation would be required to practice the full scope of the invention as claimed.

In view of the amendment to the claims, the rejection of claims under 35 USC 112, second paragraph is withdrawn.

***Claim Rejections - 35 USC § 103***

After considering the arguments in applicant's response, the rejection of claims 31, 34, and 40-47 as unpatentable over Nyeki et al is withdrawn.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1648


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/8/05

  
**MARY E. MOSHER, PH.D.**  
**PRIMARY EXAMINER**